

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 2

No new matter has been added by this amendment. Reconsideration is respectfully requested.

#### **I. Restriction Requirement**

The Examiner suggests that restriction to one of the following Groups is required under 35 U.S.C. § 121: Group I, claims 1-4, is drawn to a microencapsulated composition comprising a mixture of sorbents with affinities for uremic toxins and a bacterial source which metabolizes urea and ammonia, classified in class 435, subclass 262.5. Group II, claims 5-7, is drawn to a method of alleviating symptoms of uremia in a patient by administration of a composition comprising a mixture of sorbents with a bacterium classified in class 435, subclass 268. The Examiner suggests that these Groups are distinct because the process for using the product as claimed can be practiced with another materially different product or the product as claimed can be used in a materially different process of using that product. The Examiner suggests that urease has been shown to have a positive effect on individuals suffering from uremia.

Applicant respectfully traverses this Restriction Requirement.

MPEP §803, provides two criteria which must be met for a restriction requirement to be proper. The first is that the

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 3

inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. The prior art search performed by the Examiner in the instant case was clearly not limited to the composition of claims 1-4. The Examiner has found that urease has been shown to have a positive effect on patients suffering from uremia. Accordingly, the prior art search already conducted by the Examiner was broad enough to identify prior art not only related to claims 1-4, but also to claim 5-7. Thus, no undue burden would be placed on the Examiner by also prosecuting Group II claims in the instant application as the prior art in this area has already been searched. Accordingly, this restriction requirement does not meet both criteria required to be proper. Withdrawal of this restriction requirement is therefore respectfully requested. However, in an earnest effort to be completely responsive, Applicant affirms the election made on July 19, 2000 to prosecute Group I, claims 1-4, with traverse.

## II. Rejection of Claim 2 under 35 U.S.C. §112, 2nd paragraph

The Examiner has rejected claim 2 under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically the Examiner suggests that

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 4

the phrase "middle molecular weight molecules" is indefinite and that one having skill in the art would have trouble ascertaining what middle molecular weight molecules to which the claim was referring.

Applicant respectfully disagrees with the Examiner's suggestion that the phrase "middle molecular weight molecules" is indefinite. MPEP § 2173.02 is quite clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application; the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. Pages 8 through 16 of the specification provide various exemplary "middle molecular weight molecules" and coatings which limit "middle sized molecules" at page 9, by which one of skill in the art would clearly understand the meaning of the "middle molecular weight molecules" recited in claim 2. Examples of such coatings include alginate/alginate acid, chitosan, cellulose acetate phthalate, and hydroxyethyl cellulose, see page 9, lines 10-12. Thus, what is encompassed by "middle molecular weight molecules" would be quite clear to one of skill in the art when read in light of the teachings of the instant specification. Accordingly, claim 2 meets the requirements of 35

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 5

U.S.C. § 112, second paragraph. Withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

### III. Rejection of Claims 1-4 under 35 U.S.C. § 103

The Examiner rejected claims 1-4 under 35 U.S.C. § 103 as being unpatentable over Yatsidis et al. (1979) in view of Prakash et al. (1995) and further in view of Goldenhersh et al. Applicants disagree with the Examiner's suggestion. In accordance with MPEP § 2143 to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. The cited combination of prior art references fail to meet these basic criteria.

The Examiner suggests that Yatzidis et al teaches locust bean gum as having a beneficial effect on uremia. Prakash et al teaches a method of treating uremia by use of microencapsulated *E.coli* strain (DH5), and further suggests that Goldenhersh et al. teaches

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 6

severe adsorption competition interferes with adsorption of creatine on activated carbon, and that microencapsulated form of activated charcoal result in a lesser amount of the charcoal being administered. The Examiner suggests that combination of the instant invention components would have been obvious and that invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. Applicants respectfully traverse this rejection.

Yatzidis et al. teach a mixture comprising locust bean gum and cottonseed oil. The gum was mixed with cottonseed oil to reduce the volume of the gum in the mouth and thereby make it more palatable to the patient. Yatzidis et al. does not teach the use of an encapsulated coating, nor is a bacterial source which metabolizes urea or ammonia taught.

Prakash et al. teach a method of removing urea and ammonia using a microencapsulated *E.coli* DH5 cells. Prakash et al teaches the use of the *E.coli* cells as a sole mechanism for urea and ammonia removal. There is no teaching or suggestion that the cells could be used with sorbent materials to treat uremia. In fact to the contrary, Prakash et al. teach that adsorbent materials do not have sufficient adsorbent capacity to be useful. Goldenhersh et

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 7

al. teach that severe adsorption competition in intestinal fluids interferes with adsorption of creatine on activated carbon, and further teaches the use of encapsulated carbon to aid in efficacy of carbon adsorption. Goldenhersh et al does not teach the combination of a bacterial agent along with an adsorbant material. There is no suggestion or motivation in the teaching of Goldenhersh et al. to combine an encapsulated adsorbant with a bacterial source.

Accordingly, this combination of recited references fails to render the instant claimed invention obvious, as the only motivation to combine the teachings of Yatsidis et al., Prakash et al. (1995) and Goldenhersh et al. lies in the patent application itself. However, the teaching or suggestion to make the claimed combination must be found in the prior art, not in the applicant's disclosure. See MPEP § 2143 and *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Thus, the cited combinations of references fail to meet the criteria required to establish a *prima facie* case of obviousness. Withdrawal of these rejections under 35 U.S.C. § 103 is therefore respectfully requested.

#### V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan et al.  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
Page 8

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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